

OLYMPUS

510(k) SUMMARY

NOV - 6 2008

1. General Information

- Applicant: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan
Establishment Registration No: 8010047
- Official Correspondent: Laura Storms-Tyler
Regulatory Affairs & Quality Assurance
Olympus America Inc.
3500 Corporate Parkway, PO Box 610
Center Valley PA 18034-0610
Phone: (484) 896-5688
Facsimile: (484) 896-7128
Email: Laura.storms-tyler@olympus.com
Establishment Registration No: 2429304
- Manufacturer:
 - Light source/Video system center: SHIRAKAWA OLYMPUS CO., LTD.
3-1, Aza-Ookamiyama, Ooaza-Odakura, Nishigo-mura,
Nishishirakawa-gun, Fukushima, Japan 961-8061
Establishment Registration No: 3002808148
 - Choledoscope: Aizu Olympus Co., Ltd.
500 Aza-Muranishi, Ooaza-Iidera, Morden-cho,
Aizuwakamatsu-shi, Fukushima, Japan 965-8620
Establishment Registration No.: 9610595
- Date Prepared: April , 2008

2. Device Identification

- Device Name: CHF-V
- Common Name: CHOLEDOCHO VIDEOSCOPE
- Class: II
- Regulation Number/Name: 876.1500 Endoscope and accessories
- Product Code: NWB – Endoscope, accessories, narrow band spectrum
FBN – Choledochoscope, accessories,
- Classification Panel: Gastroenterology/Urology

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3. Legally Marketed Device to which Substantial Equivalence is Claimed

The following table shows the subject device and the predicate device to which we claim substantial equivalence.

**Table 15-1:
Primary Component & Predicate Device**

Subject Device (Name of this submission)	Predicate Device	PQ's 510(k) NDA
CHOLEDOCHO VIDEOSCOPE CHF-V	OES Nephroscope / Cystoscope Fiberscope CHF-P10	K843084

4. Device Description

The CHF-V choledochoscope is a flexible video endoscope used for endoscopic diagnosis and treatment within the bile duct. The CHF-V choledochoscope is basically identical to the predicate device, CHF Type P10 OES Nephroscope/Cystoscope Fiberscope, in intended use, specifications, performance. The optical system of the CHF-V is a charge coupled device (CCD) based system, allowing endoscopic image display on a video monitor.

The new endoscope is basically identical to each predicate device shown in Table 15-1 in intended use, and similar in specifications, performance and materials.

5. Indications for Use

CHOLEDOCHO VIDEOSCOPE CHF-V

This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bile duct.

OLYMPUS MEDICAL SYSTEMS CORP.

2951 Ishikawa-cho Hachioji-shi Tokyo, 192-8507 JAPAN

TELEPHONE +81-42-642-2694, TELEFAX +81-42-642-2307

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6. Comparison of Technological Characteristics

The CHF-V is similar to the predicate device CHF-P10 in specifications except for the material and optical system. Comparison between the subject and predicate devices is shown below.

Table 15-2. Comparison of Specifications

**Subject Device: CHOLEDODOCHO VIDEOSCOPE CHF-V
Predicate Device: OES Nephroscope / Cystoscope Fiberscope CHF-P10 (K843084)**

Specification	Subject Device (CHF-V)	Predicate Device (CHF-P10) (K843084)
Field of View	120°	90°
Direction of View	0°	0°
Optical System	Color CCD	Image guide fiber bundle
Angulation Up / Down	160° / 130°	160° / 130°
Working Length	380mm	330mm
Inner Diameter of Instrument Channel	φ2.0mm	φ2.0mm

6. Conclusion

When compared to the predicate device, the CHF-V does not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness of the device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Olympus Medical Systems Corp.
% Ms. Laura Storms-Tyler, Vice President
Regulatory Affairs & Quality Assurance
Olympus America Incorporated
3500 Corporate Parkway
P.O. Box 610
CENTER VALLEY PA 18034-0610

NOV - 6 2008

Re: K081456

Trade Name: CHF-V Choledoch Videoscope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Codes: FBN
Dated: October 6, 2008
Received: October 7, 2008

Dear Ms. Storms-Tyler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081456

Device Name: CHF-V CHOLEDOCHO VIDEOSCOPE

Indications For Use:

CHOLEDOCHO VIDEOSCOPE OLYMPUS CHF TYPE V

This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bile duct.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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J. M. Why
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K081456